Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the July 21, 2005, meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
Review of Boniva **New agent in the Bisphosphonate Class**	1. All agents in the bisphosphonate class are considered clinically equivalent in efficacy and safety. 2. Quantity limits – Place quantity limits on the bisphosphonate agents as follows: Actonel: 5mg- 30 tablets/30 days 30mg- 30 tablets/30days 35mg- 4 tablets/28 days Boniva: 2.5mg- 30 tablets/ 30 days 150mg- 1 tablet/28 days Fosamax: 5mg- 30 tablets/30 days 10mg- 30 tablets/30days 35 mg- 4 tablets/28 days 40mg- 30 tablets/30days 70mg- 4 tablets/28days 70mg- 300ml Solution/28 days 3. For any new chemical entity in the bisphosphonate class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
Review of Lunesta **New agent in the Sedative Hypnotic Class**	1. Sedative hypnotic therapy must be evaluated prior to chronic use. 2. Step therapy- Require temazepam 15 &30 mg or triazolam claim within the past 12 months prior to initiation of Ambien , Lunesta, or Sonata with the exception of pregnant women and patients > than 65 years old. 3. Consider Prior authorization requirement for **any** patient receiving > 60 days in any 365 day period for any sedative hypnotic. 4. Quantity limits- Place quantity limits on Lunesta as follows: Lunesta: 1mg- 14/14 days 2mg- 14/14 days 3mg- 14/14 days • Agents with previously established quantity limits remain in effect 5. For any new chemical entity in the sedative hypnotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.

Urinary Tract Antispasmodics Therapeutic Class Review	1. All urinary tract antispasmodics and all dosage forms are clinically equivalent in efficacy safety. 2. Step Therapy- • Require generic oxybutinin claim within the past 12 months prior to initiation of a branded product (LTC patients excluded). 3. Quantity Limits: Place quantity limits on the overactive bladder agents as follows: Oxybutynin: 5mg- 120 tablets/30 days or 600ml syrup/30 days Oxytrol.: 3.9mg- #8(patches)/30 days Detrol: 2mg and 4mg- 120tablets/30 days Detrol LA: 2mg and 4mg- 30 tablets/30 days Ditropan: 5mg-120 tablets/30 days Ditropan XL: 5, 10, & 15mg- 30 tablets/30 days Enablex: 7.5 & 15mg- 30 tablets/30 days Vesicare: 5 & 10 mg- 30 tablets/30 days 4. For any new chemical entity in the urinary tract antispasmodic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
ACEI/ ARBs Clinical Criteria	1. ACE Inhibitors and ARBs classes were reviewed by P&T in May 2004. 2. All ACE Inhibitors were considered clinically equivalent in efficacy and safety. 3. All ARBs were considered clinically equivalent in efficacy and safety. 4. Step therapy-Require an ACE claim within the past 12 months prior to initiation of an ARB therapy.
P & T Advisory Committee Recommendation Regarding New Drugs	1. Upon initial coverage by the Kentucky Medicaid program, a new drug, in any of the following drug classes, will be prior authorized and scheduled for review by the Pharmacy and Therapeutics Advisory Committee within 75 days. • NEW GENERATION ANTIDEPRESSANTS • COPD ANTICHOLINERGICS • LIPOTROPICS - NON STATINS: FIBRIC ACID DERIVATIVES • TOPICAL IMMUNOMODULATORS • ELECTROLYTE DEPLETERS • HERPES ANTIVIRALS • CHOLINESTERASE INHIBITORS: ALZHEIMER'S AGENTS • IMMUNOMODULATORS • MULTIPLE SCLEROSIS AGENTS • LIPOTROPICS - NON STATINS: NIACIN DERIVATIVES • NON-ERGOT DOPAMINE RECEPTOR AGONISTS

The following terms will be utilized within the therapeutic monograph to classify medications during Drug Class Reviews. By using these terms, the reviewer will be able to easily identify any clinical differences between the medications within the class being reviewed.

Superior - Following evidence-based review, it is determined that the drug provides a therapeutic advantage, in terms of safety and/or efficacy, over other available products within the same treatment modality.

Novel - Following evidence-based review, the drug is therapeutically equivalent in both safety and efficacy, but represents a new therapeutic option, which expands the treatment modality.

Equivalent - Following evidence-based review, it is determined that the drug is therapeutically equivalent in both safety and efficacy to other available products within the same treatment modality.

Not Essential - Following evidence-based review, it is determined that the drug has no therapeutic advantage, due to either reduced safety or efficacy, over other available products within the same treatment modality.